Kimberly Tisa/R1/USEPA/US
06/21/2005 06:32 AM

To JOHN SCHELL <js1@bbl-inc.com>
cc Mike Teague <Mike.Teague@clariant.com>, Laura Casey/DC/USEPA/US
bcc
Subject Re: Contact Info

As discussed last week, the attached memo provides the additional information Versar has indicated it needs to support the calculations in the carpet exposure scenario. Should you have any questions, please let me know. Thanks.

Clariant data needs 6202005.wpd

Kimberly Tisa, PCB Coordinator (CPT)
USEPA
1 Congress Street, Suite 1100
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617.918.1527 (PHONE)
617.918.0527 (FAX)
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JOHN SCHELL <js1@bbl-inc.com>

JOHN SCHELL
<js1@bbl-inc.com>
06/16/2005 04:04 PM

To Kimberly Tisa/R1/USEPA/US@EPA
cc Mike Teague <Mike.Teague@clariant.com>
Subject Contact Info

Kim:

Mike requested that I forward my contact information to you If you have any questions, please give me a call Thanks.

John

John D. Schell, Ph.D.
Vice President/Toxicologist
BBL Sciences
2929 Briarpark Dr., Suite 329
Houston, TX 77042
P: 713.785.1680 (X14)
F: 713.785-1640

Versar inc.

MEMORANDUM

TO:	Laura Casey	cc:	11.1126.1000.001.01 Diane Sinkowski
FROM:	Mike Koontz		Jim Buchert
DATE:	June 20, 2005		
SUBJECT:	Request for Additional Information to Support Clariant's Inhalation Exposure and Volatilization Factor Calculations Related to Total PCBs in Carpeting from Scenarios Associated with Pigment Red 144/214		

The purpose of this Memorandum is to request additional information to support the inhalation exposure and volatilization factor calculations related to total PCBs in carpeting as presented in Clariant's Revised "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" (April 11, 2005).

Owing to uncertainty in appropriate values for certain parameters that were used in exposure/risk calculations, it is important to understand the relative contributions of different exposure routes to total dose estimates. If, for example, the dominant exposure route (or routes) is one for which there is considerable uncertainty in one or more of the parameters used to calculate dose, then it may be important to examine that route more closely.

In Table 3 of the April 11, 2005, report prepared by BBL Sciences for Clariant Corporation, the acceptable concentration of tPCBs in carpet fiber is relatively insensitive to the retention factor used for the inhalation route of exposure. It was stated in the conference call on June 16, 2005, that this insensitivity is because inhalation makes only a minor contribution to the total dose. Versar requests that Clariant/BBL support this contention via calculation of the total dose and contributions of each exposure route, in mg/kg/day, for an illustrative case. Once the values have been shown for the illustrative case, it should be a simple matter for any of the parties to calculate values for other cases and thereby assess sensitivity for any route of interest.

For the illustrative calculation, it is recommended that Clariant/BBL use current worst-case estimates of 100 for the bioavailability factor and 0.01 for the retention factor, along with an assumed tPCB concentration in carpet fiber of 16.4 mg/kg, which was stated in the BBL report to be the maximum expected concentration. Values should be listed for each parameter used in the dose calculation for each route. Most of these values were shown in Table 1 of the BBL report, but certain intermediate calculations such as the volatilization factor were not shown.

Please feel free to contact me if you have any questions or comments.

Inputs:

TR	1.00E-06	TR=Target cancer risk
SF	0.07	SF=Cancer slope factor
ATnc	3650	ATnc = Averaging time for noncarcinogens (days)
ATc	25550	AT_c=Averaging time for carcinogens (days)
ED	10	ED_L=Exposure duration (carpet life; yrs)
	10	Carpet life expectancy 7- 10 years
EF	350	EF=Exposure frequency (days/yr)
IR	55	IR=Dust (soil) ingestion rate (mg/day)

AF	0.00724	AF=Soil adherence factor for children post-activity indoors on hands, arms, legs, feet (mg/cm^2)
SA	2763	SA=Contact skin surface area during warm-weather play with 32% skin exposed (cm^2/day)
BW	21.8	BW=Body weight (children 6 mnths to 12 yrs old; kg)
BioAF	range	BioAF=Bioavailablity factor (unitless)
IHR	10.42	IHR-inhalation rate (m^3/day)
VP	0.0069	VP=Vapor pressure of PCB44/70 mixture (Pa)
dw	0.0129	d_w=Carpet thickness (m)
Mass	1700000	Carpet mass=Carpet area mass (face weight; kg/m^2)
AE	126	AE=Complete room air exchange rate (1/week; based on recommended 0.35 exchanges/hr)

Cg	see below	C_g=Air concentration in an enclosed space after 7 days post-installation (mg/m^3)
DERM	0.14	DERM= Dermal uptake factor (US EPA)
RF	range	RF = Retention Factor (unitless)

Volatilization Factor
Based on Empirical Data, Vapor Pressure, and Mass Balance Models

1.445152E+05 Surface-air partition coefficient for carpet (unitless) $Kca=(k_s/k_d)/dw = 10^{3.82-0.62logVP}$

$k_s/k_d=M/C_{air}=d_w*10^{3.83-0.62logVP}$

$M\ (mg/m2)=C_{air}*d_w*10^{3.83-0.62logVP}$

$M/C_{air} = d_w*10^{3.83-0.62logVP}$

$C_{carpet}\ (mg/kg) = M\ (mg/m2)/Mass_c\ (kg/m2)$

VF **137745.099178** $VF\ (m3/kg)=[d_w\ (m)*10^{3.83-0.62logVP}]/[Mass_c(mg/m2)/1000000\ (mg/kg)]/AE$

						Lifetime Cancer Risk							
	Slope Factor (per mg/kg-day)	Bioavailability	Dermal Absorption Factor	Retention Factor	Carpet Concentration (mg/kg)	Ingestion	% of Total	Dermal	% of Total	Inhalation	% of Total	Total Lifetime Cancer Risk	
Chemicals	SF	Bio	Derm	RF	Conc								
PCBs	0.07	0.01	0.14	0.001	664	1.6E-07	16.1%	8.2E-07	81.7%	2.2E-08	2.2%	1.0E-06	100.0%
PCBs	0.07	0.05	0.14	0.001	404	4.9E-07	48.9%	5.0E-07	49.8%	1.3E-08	1.3%	1.0E-06	100.0%
PCBs	0.07	0.1	0.14	0.001	271	6.6E-07	65.7%	3.3E-07	33.4%	9.0E-09	0.9%	1.0E-06	100.0%
PCBs	0.07	0.5	0.14	0.001	74.8	9.0E-07	90.5%	9.2E-08	9.2%	2.5E-09	0.2%	1.0E-06	100.0%
PCBs	0.07	1	0.14	0.001	39.3	9.5E-07	95.0%	4.8E-08	4.8%	1.3E-09	0.1%	1.0E-06	100.0%

						Lifetime Cancer Risk							
	Slope Factor (per mg/kg-day)	Bioavailability	Dermal Absorption Factor	Retention Factor	Carpet Concentration (mg/kg)	Ingestion	% of Total	Dermal	% of Total	Inhalation	% of Total	Total Lifetime Cancer Risk	
Chemicals	SF	Bio	Derm	RF	Conc								
PCBs	0.07	0.01	0.14	0.005	610	1.5E-07	14.8%	7.5E-07	75.1%	1.0E-07	10.1%	1.0E-06	100.0%
PCBs	0.07	0.05	0.14	0.005	384	4.6E-07	46.4%	4.7E-07	47.2%	6.4E-08	6.4%	1.0E-06	100.0%
PCBs	0.07	0.1	0.14	0.005	262	6.3E-07	63.4%	3.2E-07	32.3%	4.4E-08	4.4%	1.0E-06	100.0%
PCBs	0.07	0.5	0.14	0.005	74.1	9.0E-07	89.6%	9.1E-08	9.1%	1.2E-08	1.2%	1.0E-06	100.0%
PCBs	0.07	1	0.14	0.005	39.1	9.5E-07	94.5%	4.8E-08	4.8%	6.5E-09	0.7%	1.0E-06	100.0%

						Lifetime Cancer Risk							
	Slope Factor (per mg/kg-day)	Bioavailability	Dermal Absorption Factor	Retention Factor	Carpet Concentration (mg/kg)	Ingestion	% of Total	Dermal	% of Total	Inhalation	% of Total	Total Lifetime Cancer Risk	
Chemicals	SF	Bio	Derm	RF	Conc								
PCBs	0.07	0.01	0.14	0.01	554	1.3E-07	13.4%	6.8E-07	68.2%	1.8E-07	18.4%	1.0E-06	100.0%
PCBs	0.07	0.05	0.14	0.01	361	4.4E-07	43.6%	4.4E-07	44.4%	1.2E-07	12.0%	1.0E-06	100.0%
PCBs	0.07	0.1	0.14	0.01	251	6.1E-07	60.7%	3.1E-07	30.9%	8.4E-08	8.4%	1.0E-06	100.0%
PCBs	0.07	0.5	0.14	0.01	73.2	8.9E-07	88.5%	9.0E-08	9.0%	2.4E-08	2.4%	1.0E-06	100.0%
PCBs	0.07	1	0.14	0.01	38.8	9.4E-07	93.9%	4.8E-08	4.8%	1.3E-08	1.3%	1.0E-06	100.0%

						Lifetime Cancer Risk							
	Slope Factor (per mg/kg-day)	Bioavailability	Dermal Absorption Factor	Retention Factor	Carpet Concentration (mg/kg)	Ingestion	% of Total	Dermal	% of Total	Inhalation	% of Total	Total Lifetime Cancer Risk	
Chemicals	SF	Bio	Derm	RF	Conc								
PCBs	0.07	0.01	0.14	1	28.8	7.0E-09	0.7%	3.5E-08	3.5%	9.6E-07	95.8%	1.0E-06	100.0%
PCBs	0.07	0.05	0.14	1	28.0	3.4E-08	3.4%	3.4E-08	3.4%	9.3E-07	93.2%	1.0E-06	100.0%
PCBs	0.07	0.1	0.14	1	27.1	6.6E-08	6.6%	3.3E-08	3.3%	9.0E-07	90.1%	1.0E-06	100.0%
PCBs	0.07	0.5	0.14	1	21.5	2.6E-07	26.0%	2.6E-08	2.6%	7.2E-07	71.4%	1.0E-06	100.0%
PCBs	0.07	1	0.14	1	17.0	4.1E-07	41.2%	2.1E-08	2.1%	5.7E-07	56.7%	1.0E-06	100.0%

INPUTS

TR	1.00E-06	TR=Target cancer risk
SF	0.07	SF=Cancer slope factor
ATnc	3650	ATnc = Averaging time for noncarcinogens (days)
ATc	25550	AT_C=Averaging time for carcinogens (days)
ED	10	ED_L=Exposure duration (carpet life; yrs)
	10	Carpet life expectancy 7- 10 years
EF	350	EF=Exposure frequency (days/yr)
IR	55	IR=Dust (soil) ingestion rate (mg/day)
AF	0.00724	AF=Soil adherence factor for children post-activity indoors on hands, arms, legs, feet (mg/cm^2)
SA	2763	SA=Contact skin surface area during warm-weather play with 32% skin exposed (cm^2/day)
BW	21.8	BW=Body weight (children 6 mnths to 12 yrs old; kg)
BioAF	range	BioAF=Bioavailablity factor (unitless)
IHR	10.42	IHR-inhalation rate (m^3/day)
VP	0.0069	VP=Vapor pressure of PCB44/70 mixture (Pa)
dw	0.0129	d_w=Carpet thickness (m)
Mass	1700000	Carpet mass=Carpet area mass (face weight; kg/m^2)
AE	126	AE=Complete room air exchange rate (1/week; based on recommended 0.35 exchanges/hr)
Cg	see below	C_g=Air concentration in an enclosed space after 7 days post-installation (mg/m^3)
DERM	0.14	DERM= Dermal uptake factor (US EPA)
RF	range	RF = Retention Factor (unitless)

Volatilization Factor
Based on Empirical Data, Vapor Pressure, and Mass Balance Models

1.445152E+05 Surface-air partion coefficient for carpet (unitless) $Kca=(k_s/k_d)/dw = 10^{3.82-0.62logVP}$

$k_s/k_d=M/C_{air}=d_w*10^{3.83-0.62logVP}$

$M\ (mg/m2)=C_{air}*d_w*10^{3.83-0.62logVP}$

$M/C_{air} = d_w*10^{3.83-0.62logVP}$

$C_{carpet}\ (mg/kg) = M\ (mg/m2)/Mass_c\ (kg/m2)$

VF **137745.099178** $VF\ (m3/kg)=[d_w\ (m)*10^{3.83-0.62logVP}]/[Mass_c(mg/m2)/1000000\ (mg/kg)]/AE$

	Reference Dose (mg/kg-day)	Bioavailability	Dermal Absorption Factor	Retention Factor	Carpet Concentration (mg/kg)	Hazard Quotient						Total Hazard Index	
						Ingestion	% of Total	Dermal	% of Total	Inhalation	% of Total		
Chemicals	RfD	Bio	Derm	RF	Conc								
PCBs	0.00002	0.01	0.14	0.001	133	1.6E-01	16.1%	8.2E-01	81.7%	2.2E-02	2.2%	1.0E+00	100.0%
PCBs	0.00002	0.05	0.14	0.001	80.8	4.9E-01	48.9%	5.0E-01	49.8%	1.3E-02	1.3%	1.0E+00	100.0%
PCBs	0.00002	0.1	0.14	0.001	54.3	6.6E-01	65.7%	3.3E-01	33.4%	9.0E-03	0.9%	1.0E+00	100.0%
PCBs	0.00002	0.5	0.14	0.001	15.0	9.1E-01	90.5%	9.2E-02	9.2%	2.5E-03	0.2%	1.0E+00	100.0%
PCBs	0.00002	1	0.14	0.001	7.9	9.6E-01	95.0%	4.9E-02	4.8%	1.3E-03	0.1%	1.0E+00	100.0%

	Reference Dose (mg/kg-day)	Bioavailability	Dermal Absorption Factor	Retention Factor	Carpet Concentration (mg/kg)	Hazard Quotient						Total Hazard Index	
						Ingestion	% of Total	Dermal	% of Total	Inhalation	% of Total		
Chemicals	RfD	Bio	Derm	RF	Conc								
PCBs	0.00002	0.01	0.14	0.005	122	1.5E-01	14.8%	7.5E-01	75.1%	1.0E-01	10.1%	1.0E+00	100.0%
PCBs	0.00002	0.05	0.14	0.005	76.7	4.6E-01	46.4%	4.7E-01	47.2%	6.4E-02	6.4%	1.0E+00	100.0%
PCBs	0.00002	0.1	0.14	0.005	52.4	6.3E-01	63.4%	3.2E-01	32.3%	4.4E-02	4.4%	1.0E+00	100.0%
PCBs	0.00002	0.5	0.14	0.005	14.8	9.0E-01	89.6%	9.1E-02	9.1%	1.2E-02	1.2%	1.0E+00	100.0%
PCBs	0.00002	1	0.14	0.005	7.8	9.4E-01	94.5%	4.8E-02	4.8%	6.5E-03	0.7%	1.0E+00	100.0%

	Reference Dose (mg/kg-day)	Bioavailability	Dermal Absorption Factor	Retention Factor	Carpet Concentration (mg/kg)	Hazard Quotient						Total Hazard Index	
						Ingestion	% of Total	Dermal	% of Total	Inhalation	% of Total		
Chemicals	RfD	Bio	Derm	RF	Conc								
PCBs	0.00002	0.01	0.14	0.01	111	1.3E-01	13.4%	6.8E-01	68.2%	1.8E-01	18.4%	1.0E+00	100.0%
PCBs	0.00002	0.05	0.14	0.01	72.1	4.4E-01	43.6%	4.4E-01	44.4%	1.2E-01	12.0%	1.0E+00	100.0%
PCBs	0.00002	0.1	0.14	0.01	50.2	6.1E-01	60.7%	3.1E-01	30.9%	8.4E-02	8.4%	1.0E+00	100.0%
PCBs	0.00002	0.5	0.14	0.01	14.6	8.8E-01	88.5%	9.0E-02	9.0%	2.4E-02	2.4%	1.0E+00	100.0%
PCBs	0.00002	1	0.14	0.01	7.8	9.4E-01	93.9%	4.8E-02	4.8%	1.3E-02	1.3%	1.0E+00	100.0%

	Reference Dose (mg/kg-day)	Bioavailability	Dermal Absorption Factor	Retention Factor	Carpet Concentration (mg/kg)	Hazard Quotient						Total Hazard Index	
						Ingestion	% of Total	Dermal	% of Total	Inhalation	% of Total		
Chemicals	RfD	Bio	Derm	RF	Conc								
PCBs	0.00002	0.01	0.14	1	5.8	7.0E-03	0.7%	3.6E-02	3.5%	9.6E-01	95.8%	1.0E+00	100.0%
PCBs	0.00002	0.05	0.14	1	5.6	3.4E-02	3.4%	3.4E-02	3.4%	9.3E-01	93.2%	1.0E+00	100.0%
PCBs	0.00002	0.1	0.14	1	5.4	6.5E-02	6.6%	3.3E-02	3.3%	9.0E-01	90.1%	1.0E+00	100.0%
PCBs	0.00002	0.5	0.14	1	4.3	2.6E-01	26.0%	2.6E-02	2.6%	7.2E-01	71.4%	1.0E+00	100.0%
PCBs	0.00002	1	0.14	1	3.4	4.1E-01	41.2%	2.1E-02	2.1%	5.7E-01	56.7%	1.0E+00	100.0%

John Schell

① Retention Factor taken from a former pesticide model that was developed. Using ~~1%~~ 1% RF would consider 30% volatization on a yearly basis (30% over 10yrs)

Mike Koontz

② RF wasn't considered the volatalized fraction but % released over time.

~~Glenn~~

RF is in daily dose calculation.

Didi

probably low.

Laura Casey/DC/USEPA/US
06/10/2005 02:32 PM

To Kimberly Tisa/R1/USEPA/US@EPA, buchejam@versar.com, DSinkowski@versar.com, KOONTMIK@versar.com, Mike.Teague@clariant.com

cc

bcc

Subject EPA/Clariant Conference Call - Thurs. June 16th

Good Afternoon

I have scheduled the conference call for Thursday, June 16th from 2:30 to 4:30 pm. Attached is the call-in number and instructions.

Clariant Call 6-16.wpd

Thanks

Laura Casey
Chemist
US EPA
202-566-1982

. . . . . .

WE ARE NOW ON EMAIL - GROUP AUDIO-TELECONF
Audio Teleconference Reservations
EPA Washington Telecommunications Center (WTC)

DATE: June 10, 2005

TO: **Laura Casey**

FROM: Audio Teleconference Center
STG Incorporated, Contract No. 68-W-01-022

You have reserved 8 lines from 2:30p **.m. to 4:30p .m.** (Eastern Time Zone) call in number **(202) 275-0166, with no access code, on June 16, 2004.**

NOTE: Because you have not been assigned an access code, just have your callers stay on the line, ignore the message to enter a code, and when one of our operators answers have them state that the call is operator assisted and give the operator the subject of the call and your name.

If your reservation is not going to be used as scheduled, OR if you need to change your reservation, please call us at **(202) 272-CONF (2663)** as soon as possible, so that our staff can make the necessary changes. All reservations for audio conferences will incur a charge, unless the reservation is canceled prior to the day of the call.

Please note that all teleconferences are monitored for audio quality by EPA's telecommunications service contractors, therefore discussions of any sensitive or restricted information during a conference call is prohibited.

The audio teleconferencing system allows the operators to assist conferees during their conferences. To request assistance, **press the asterisk (*) and zero (0) keys** on your touch-tone telephone.This will alert the operator assigned to your lines. Unfortunately, this feature does not work on all speakerphones, electronic telephone systems, or rotary style telephones. If this feature is not available, you must call our hotline at **(202) 272-0168.**

Kimberly Tisa/R1/USEPA/US
06/09/2005 07:16 AM

To mike.teague@clariant.com
cc Tom Olivier/R1/USEPA/US, Marianne Milette/R1/USEPA/US, Laura Casey/DC/USEPA/US
bcc
Subject Comments on Risk Exposure Model

Mike-

Attached are comments on your April 11, 2005 Exposure and Screening Model for the Carpet Fiber and Food Wrap Scenarios. As indicated to you during our discussion last week, I would like to set up a conference call with Clariant, BBL, Versar and EPA to discuss these outstanding issues. If we can't readily resolve this via conference, EPA is prepared to have a meeting in Washington to continue these discussions.

I would propose a conference call with all parties on**Tuesday, June 14**. Please let me know what time would be best for you and I will see if we can accommodate.

Clariant carpet fiber and food wrap - april 11, 2005.wpd

Kimberly Tisa, PCB Coordinator (CPT)
USEPA
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Boston, MA 02114-2023

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617.918.0527 (FAX)
e-mail: tisa.kimberly@epa.gov

Versar inc.

MEMORANDUM

TO: Laura Casey cc: Jim Buchert
11.1126.1000.001.01

FROM: Mike Koontz/Diane Sinkowski

DATE: June 6, 2005

SUBJECT: Review of "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" (April 11, 2005)

As requested, Versar has reviewed the revised calculations provided in the April 11, 2005, Clariant report. Remaining issues that should be addressed or discussed are as follows:

1. Without supporting information, such as laboratory studies or direct measurements, on PCB retention in carpeting, Table 3 should include calculations of acceptable PCB concentrations assuming additional retention factors, including a worst-case retention factor of 100 percent (i.e., 1.0).

2. We are not comfortable with the inclusion of the assumed air exchange rate of 126 air exchanges per week into the Bennet and Furtaw equation calculating the volatilization factor (VF) (see Equations 5 through 7, pages 2-3 and 2-4). In particular, the use of a weekly value seems somewhat arbitrary and the units (air exchanges per week) do not produce the appropriate units for VF (m^3/kg), as demonstrated below.

   The value for VF can be determined from the following relationship, given as Equation 7 in the report:

   $$VF = (d_W * 10^{3.82 - 0.62 \log VP} * AE) / FW$$ Equation 7, page 2-4

   Where:

   d_W=carpet thickness in m,
   VP=vapor pressure in Pa,
   AE=air exchanges per week, and
   FW=carpet face weight in kg/m^2.

Using 0.01286 m for d_W, 0.0069 Pa for VP, 126/week for AE, and 1.7 kg/m^2 for FW, as given in the report, we get the following value for VP:

$VF = [(0.01286\ m) * (10^{3.82 - 0.62 \log (0.0069\ Pa)} * (126/week)] / 1.7\ kg/m^2 = 137{,}745\ m^3$ /kg-week

The calculated value for VF is not presented in the report, so the resulting units are not presented. However, VF, as used in Equations 1, 7, and 9, must have units of m^3/kg. Thus, further justification of this calculation is necessary.

Please feel free to contact us at 703-750-3000 x 737 if you have any questions or comments.

Laura Casey/DC/USEPA/US
06/02/2005 10:25 AM

To Kimberly Tisa/R1/USEPA/US@EPA
cc
bcc
Subject Fw: Clariant comments

See below. All set for this afternoon? I have a mtg from 12-1 but I'll skip out a few minutes early.

Laura
----- Forwarded by Laura Casey/DC/USEPA/US on 06/02/05 10:24 AM -----

Diane Sinkowski
<DSinkowski@versar.com>
06/02/05 10:10 AM

To Laura Casey/DC/USEPA/US@EPA
cc James Buchert <BUCHEJAM@versar.com>, mkoontz@versar.com
Subject clariant comments

Hi Laura,

I meant to get this to you yesterday, but the Versar e-mail went down at the end of the day. Mike and I would be happy to walk you and Kim through the calculations over the phone.

Didi

Diane S. Sinkowski
Environmental Engineer
Exposure/Risk Assessment Division
Versar, Inc.
6850 Versar Center
Springfield, VA 22151
Phone: 703-750-3000, ext. 737
Fax: 703-642-6954
dsinkowski@versar.com

comments on Clariant_April 11, 2005.wpd

Versar inc.

MEMORANDUM

TO: Laura Casey cc: Jim Buchert
11.1126.1000.001.01

FROM: Mike Koontz/Diane Sinkowski

DATE: June 2, 2005

SUBJECT: Review of Inhalation Exposure and Volatilization Factor Calculations Related to Total PCBs in Carpeting (from Clariant's Revised "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" (April 11, 2005))

As requested, Versar has reviewed the revised inhalation exposure risk calculations provided in the April 11, 2005, Clariant report. Inhalation exposure assessments can be done in a different way than in the Clariant report. In the comments below we will first calculate an "acceptable concentration" according to the methods described in the report. Next, we will derive an alternative estimate of the expected indoor-air concentration by calculating a steady-state or constant total PCB (tPCB) emission rate from the carpeting and assuming that some fraction of the contaminant will eventually volatilize.

The following relationship between the VF (in m^3/kg), mass of tPCBs in the carpet (M_{cw}, in mg/kg), and acceptable concentration of tPCBs in air (C_g, in mg/m^3), is taken from the Clariant report:

$$VF = M_{cw} / C_g \qquad \text{Equation 1 (Equation 8, Clariant Report)}$$

Equation 1 can be rearranged to solve for C_g, as follows:

$$C_g = M_{cw} / VF \qquad \text{Equation 2}$$

The value given for M_{cw} in the report is 16.4 mg/kg. The value for VF can be determined from the following relationship, as given in the report:

$$VF = (d_w * 10^{3.82 - 0.62 \log VP} * AE) / FW \qquad \text{Equation 3 (Equation 7, Clariant Report)}$$

Where d_w is carpet thickness in m, VP is vapor pressure in Pa, AE is air exchanges per week, and FW is carpet face weight in kg/m^2. Using values of 0.01286 m for d_w, 0.0069 Pa for VP, 126/week for AE, and 1.7 kg/m^2 for FW, as given in the report, the VF from Equation 3 can be calculated:

$$VF = [(0.01286\ m) * (10^{3.82 - 0.62 \log(0.0069\ Pa)} * 126/week)] / 1.7\ kg/m^2 = 137{,}745\ m^3/kg$$

Section 2.2.4 of the Clariant report cites 18 air exchanges per day for a residence (from Murray and Burmaster, 1995) as a basis for coming up with a weekly dilution factor (126 air exchanges (AE) per week, or 126/week in the calculation, if we understand it correctly). We are not sure that this use of air exchange is technically correct. The authors say that AE is unitless whereas we am accustomed to seeing it expressed in relation to time (e.g., air exchanges per week). Further, the authors seem to be arguing that this weekly "dilution factor" is tantamount to assuming that the tPCB load will be renewed every 7 days.

Substituting that value into Equation 2 gives an acceptable concentration of $1.2x10^{-4}$ mg/m^3:

$$C_g = M_{cw} / VF = (16.4\ mg/kg)/(137{,}745\ m^3/kg) = 0.00012 \text{ or } 1.2x10^{-4}\ mg/m^3$$

The average daily dose (ADD) can then be calculated:

ADD = (Cg)*(inhalation rate)*(exposure frequency)*(exposure duration)/[(body weight)*(averaging time)]

$$ADD = (1.2x10^{-4}\ mg/m^3)*(10.4\ m^3/d)*(365\ d/yr)*(10\ yr)/[(21.8\ kg)*(10\ yr*365\ d/yr)]$$

$$ADD = 5.7x10^{-5}\ mg/kg/day$$

The is slightly above the non-cancer reference dose (RfD) 2.0×10^{-5} mg/kg/d and would correspond to a hazard quotient (HQ) of 2.8. If it is assumed that 1 percent of the PCBs are liberated (i.e., volatilized), then the HQ would be 0.028. The lifetime average daily dose (LADD) would be calculated as follows:

LADD = (Cg)*(inhalation rate)*(exposure frequency)*(exposure duration)/[(body weight)*(lifetime)]

$$LADD = (1.2x10^{-4}\ mg/m^3)*(10.4\ m^3/d)*(365\ d/yr)*(10\ yr)/[(21.8\ kg)*(70\ yr*365\ d/yr)]$$

$$LADD = 8.2x10^{-6}\ (mg/kg/d)$$

Multiplying by the slope factor of 0.4 $(mg/kg/d)^{-1}$ for evaporated PCBs, the estimated cancer risk is $3.3x10^{-6}$. Again, if it is assumed that only 1 percent of the PCBs are volatilized, then the cancer risk becomes $3.3x10^{-8}$.

As can be seen from these calculations, if it is assumed that all the PCBs are volatilized the cancer and non-cancer risks are above "acceptable" levels. If only 1 percent of the tPCBs are volatilized, the risks fall below levels of concern (i.e, HQ = 1.0 and cancer risk = $1x10^{-6}$).

The following is a way to calculate a steady-state or constant indoor-air concentration from the information provided in the report. For simplicity, assume that the residence consists of one small bedroom with a length of 3 m, a width of 4 m, and a height of 2.5 m (the exact dimensions

do not matter, as carpet area scales to volume). That gives a carpet area of 12 m^2 and a volume of 30 m^3. Assume an air exchange rate (AER) of 0.45/hour, a typical or central value as given in the *Exposure Factors Handbook* (EPA, 1997). The following equation can be used to estimate the steady-state concentration (C_{ss}) over the 10-year life of the carpet:

C_{ss} = Emiss Rate (mg/hr) / [Volume (m^3) * AER (1/hr)] Equation 4

To get the hourly emission rate (Emiss Rate), we need to take the tPCB mass in the carpet and divide by the 10-year emissions life of the carpet (87,600 hours). We'll assume for now that all tPCBs are liberated, and can adjust for that at the end with a simple multiplier (e.g., 0.01 if 1% is assumed to be liberated). The tPCB mass is M_{cw} (16.4 mg/kg) * FW (1.7 kg/m^2) * carpet area (12 m^2), or 334.6 mg. Dividing the mass by 87,600 hours gives an emission rate of 0.0038 mg/hr, leading to a C_{ss} estimate of 0.00028 mg/m^3:

C_{ss} = [(16.4 mg/kg)*(1.7 kg/m^2)*(12 m^2)/(87,600 hr]/[(30 m^3)*(0.45/hr)]

C_{ss} = 0.00028 or $2.8x10^{-4}$ mg/m^3

The ADD can then be calculated:

ADD = (Css)*(inhal. rate)*(exposure freq.)*(exposure duration)/[(body wt.)*(averaging time)]

ADD = ($2.8x10^{-4}$ mg/m^3)*(10.4 m^3/d)*(365 d/yr)*(10 yr)/[(21.8 kg)*(10 yr*365 d/yr)]

ADD = 0.00013 or $1.3x10^{-4}$ mg/kg/day

This value is less than the RfD of 2.0×10^{-5} mg/kg/d and would result in a HQ of 6.7. If it is assumed that only 1 percent of the tPCB are available for volatilization, then the HQ would be 0.067.

Similarly, the LADD can be calculated:

LADD = (Css)*(inhal. rate)*(exposure freq.)*(exposure duration)/[(body wt.)*(lifetime)]

LADD = ($2.8x10^{-4}$ mg/m^3)*(10.4 m^3/d)*(365 d/yr)*(10 yr)/[(21.8 kg)*(70 yr*365 d/yr)]

LADD = $1.9x10^{-5}$ (mg/kg/d)

Multiplying by the slope factor of 0.4 $(mg/kg/d)^{-1}$ for evaporated PCBs, the estimated cancer risk is $7.7x10^{-6}$. Again, if only 1 percent of the PCBs are liberated, then the cancer risk would be $7.7x10^{-8}$.

The above is only the inhalation contribution; the routes of ingestion and dermal contact also need to be considered. In lieu of the "back-calculation" approach used in the report, we suggest

that the more straightforward approach illustrated above for inhalation be taken for each of the routes. In this way, it is easy to see how the various factors work together to determine doses by each route and how each route (with its attendant uncertainties) contributes to the total estimated dose, which in turn can be directly compared with the RfD or the cancer risk may be calculated.

Please feel free to contact me if you have any questions or comments at 703-750-3000 x 737.

Versar inc.

May 12, 2005

Initial comments on carpet fiber inhalation exposure and volatilization factor by Michael Koontz (GEOMET Technologies) from review of Clariant's revised "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food WrapScenarios Associated with Pigment Red 144/214" (April 11, 2005)

The calculations relating to determination of the volatilization factor (VF) appear to be mathematically correct, and sources for their derivation (e.g., Bennet and Furtaw, 2004) adequately documented. There is one error in the units cited – the desorption coefficient or rate constant (k_d) used in Equation 3 should have units of 1/hr rather than m/hr – but the calculations still appear to be correct as shown.

The bigger concern relates to two other factors used in the assessment for which the rationale and choice of factors is not clearly stated, or at least is not well understood by me.

The first of these is the retention factor (RF) that is used in Equation 1. The authors state on page 2-4 that the largest value assumed for the RF is 0.01, which I believe is tantamount to assuming that 99 percent of the total PCBs (tPCBs) in the carpet fiber are never released. Although the relatively low volatility of tPCBs argues that some fraction indeed may never be liberated, an RF value of 0.01 strikes me as unreasonably low for an initial, conservative assessment.

The second factor of concern is the dilution factor (AE) that is used in Equation 7 for calculation of the VF. In Section 2.2.4 the authors cite 18 air exchanges per day for a residence (from Murray and Burmaster, 1995) as a basis for coming up with a weekly dilution factor (126 air exchanges per week, or 1/126 in the calculation if I understand it correctly). I'm not sure that this use of air exchange is technically correct. The authors say that AE is unitless whereas I am accustomed to seeing it expressed in relation to time (e.g., air exchanges per week). Further, the authors seem to be arguing that this weekly "dilution factor" is tantamount to assuming that the tPCB load will be renewed every 7 days. I'm not sure I buy that either, and would need to do further research myself or have it demonstrated to me mathematically.

In the past, when I've done inhalation exposure assessments, I've gone about it in an entirely different way. First, I assume an emission rate per unit time and per unit carpet surface area (e.g., $mg/m^2/hr$) along with surface area for the carpet (m^2), house volume (m^3), and an air exchange rate (in air changes per hour or 1/hr). The carpet surface area will, of course, scale to house volume. One can then derive an estimate of the steady-state indoor-air concentration (usually adequate for initial exposure/risk calculations) by assuming that some fraction of the contaminant will eventually volatilize. The equation would be as follows:

Concentration (mg/m^3) = (Emission Rate * Carpet Area) / (House Volume * Air Exchange Rate)

In reality the concentration probably will decline over time, but assuming a constant concentration will not alter the results drastically. The emission rate is nothing more than the chemical weight in the carpet multiplied by the fraction assumed to volatilize and divided by the carpet's lifetime (e.g., 10 years). Central values for the house volume (doesn't matter as carpet area scales to volume anyway) and air exchange rate (e.g., from EPA's *Exposure Factors Handbook*) would be appropriate here. The results will be sensitive to is the fraction assumed to volatilize, and I would argue that 0.01 is simply too low. There should be some empirical data available on which to base a reasonable estimate.

Of interest would be how the concentration value, as calculated in the above equation, compares to a concentration calculated from the various factors (VF, dilution, etc.) that are used by the authors of the report. If the results do not agree within a factor of two or so then something is amiss in my opinion.

MEMORANDUM

To: Mr. Jim Buchert, Versar, Inc.

From: Laura Casey, OPPT/NPCD/FOB

RE: Technical Direction to Work Assignment 0-1

Subject: Clariant Corporation, Coventry, Rhode Island

EPA-Region 1 has received from the Clariant Corporation its response to Versar's March 18, 2005 comments on the *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios* dated February 2005 (*Exposure Assessment)* associated with Clariant's Red Pigments. Clariant has also provided a revised *Exposure Assessment* incorporating Versar's comments, as applicable. EPA will provide both the response and the revised *Exposure Assessment* to Versar under separate cover.

Please review these documents for the following:

- Please review the response and the revised *Exposure Assessment* and determine if Clariant has adequately addressed Versar's comments from March 18, 2005 .

Due Date: Please turn the review of these documents around by **May 13, 2005**. If there are any questions regarding this due date, please contact me at 202-566-1982.

Technical questions relating to this project may be addressed directly to Kim Tisa in Region 1 at 617-918-1527 or by e-mail at tisa.kimberly@epa.gov.

EXPOSURE AND SCREENING-LEVEL RISK ASSESSMENT FOR CARPET FIBER AND FOOD WRAP SCENARIOS ASSOCIATED WITH PIGMENT RED 144/214

Prepared for Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205

Prepared by BBL Sciences

April 11, 2005

Table of Contents

1. Introduction

Clariant Corporation (Clariant) manufactures a wide range of specialty chemicals, including pigments, for industrial and household products. Two of these pigments, Pigment Red 144 and 214, have been produced at the Coventry, Rhode Island facility since about 2002. The synthesis of these di- and trichloroaniline-based pigments has the potential to inadvertently generate several congeners of polychlorinated biphenyls (referred to as total PCBs or "tPCBs"). This has been recognized by the United States Environmental Protection Agency (USEPA) and accounted for in its rulemakings (48 Federal Register 50846, November 1, 1983). Recently, Clariant's Coventry facility discovered that approximately 19 commercial lots of pigment formula contained tPCBs in excess of the 50-ppm maximum permitted concentration. Although Clariant halted the production of these pigments after this discovery on September 9, 2003, certain amounts of the product were released into the stream of commerce. Clariant notified its direct customers regarding the problem and requested the return of any unused pigment material. Clariant also accepted returns of processed materials containing the pigment. Furthermore, Clariant performed several risk assessments of the pigments' impact on the firm's manufacturing processes, as well as on some end-use applications.

To assess the likelihood for exposure and risk to human receptors associated with the potential release from the non-compliant pigment, Clariant constructed a Conceptual Exposure Model (CEM) (Blasland, Bouck & Lee, Inc. [BBL], 2004). A CEM forms the basis for identifying exposure scenarios that must be evaluated in a risk assessment context. Developed from existing information and relevant data, a CEM characterizes all potential or suspected sources of a chemical (or chemicals) of concern, types and concentrations of chemicals detected in primary products, transportation and distribution of primary products to secondary users, potentially affected media, potential exposure pathways, and potential receptors. The objective of a pigment-specific CEM is to evaluate existing product-specific data to develop an understanding of the potential nature, extent, and distribution of tPCB-containing products and to identify significant data gaps. The exposure scenarios that are identified during the development of a CEM are a function of the potentially exposed population, the quantities of the product sold, the possible routes of exposure to chemicals of concern, and the pathways by which chemicals of concern reach a human receptor.

The CEM (BBL, 2004) identified fiber/carpet yarn and food wrap as two scenarios that required further attention in a more detailed analysis. The current screening-level risk assessment fulfills that requirement by conducting separate exposure and risk assessments for children potentially exposed to carpet fiber and for the general population potentially exposed to food wrap. The goal of this screening-level risk assessment is to

calculate risk-based levels of tPCBs in carpet yarn and fiber using cancer and non-cancer risk/hazard thresholds and children-specific exposure factors. For the food wrap scenario, a separate risk assessment is performed using information published in the Federal Register (62 Fed. Reg. 9365, March 3, 1997) and the maximum concentration of tPCBs contained in the tinted food wrap.

One concern expressed by the USEPA in its review of the CEM was the potential for the release of pigment from a production facility, and for subsequent exposure via fugitive dust. However, this is not considered a potential complete exposure pathway for the following reasons. First, the dyes containing Pigment Red 144 and 214 are no longer produced with concentrations of tPCBs that exceed the regulatory limit, and the large proportion of pigments not incorporated into end products have been returned to the producer. Because Clariant is not aware of any spills reported at any production facility, and the contaminated pigments are no longer produced, the potential for a "release from production activities" is extremely minute. Second, the pigments were not produced in the quantity that would result in large amounts of material to be stored or unused, thus reducing the potential for a major spill. Also, because it was a valued product, the the material was handled so as to limit the loss of material during the production activities. Finally, Pigment Red 144 and 214 are brightly colored powder pigments; if there had been a spill, it would not have gone unnoticed, and it would have been cleaned up right away. Therefore, a spill would not represent a long-term exposure to workers.

Because of the unique nature of the exposure scenario, many of the parameters needed to quantify risks, or calculate risk-based concentrations, are not readily available. Due to this lack of information, it was necessary to estimate certain key variables using best professional judgment. This resulted in the introduction of some uncertainty. Therefore, the estimated variables were typically intentionally overestimated, and they represented high-end exposure conditions. Addressing uncertainty in this fashion is consistent with USEPA recommendations and guidance (USEPA, 2001). Because of its conservative approach, this assessment is reflective of the screening-level step in the human health risk assessment process. The result of this redundant conservatism is risk-based concentrations that do not represent toxicological thresholds, but rather levels that are clearly without risks. Identification of pathways and chemical concentrations that are without significant risks is the purpose of the screening-level risk assessment.

The current screening-level risk assessment focuses on tPCBs from Pigment Red 144 and 214. From a risk perspective, tPCBs are considered the chemicals of potential concern. In particular, because PCB congeners 44 and 70 make up about 90% of the tPCBs found in the pigments, these two congeners are used to characterize the physico-chemical properties of the tPCBs contained in the pigment.

2. Carpet Scenario

The primary receptors for this analysis are young children (1 to 10 years old), who may be exposed to tPCBs in the pigments via daily activities on carpeted surfaces. This potentially highly exposed population subgroup was chosen to reflect the conservative nature of the screening-level risk assessment. The activities assumed to lead to potential exposure consist of:

1. Mouthing of carpet surfaces, toys, hands, and feet, leading to the ingestion of the associated carpet fiber and dust;
2. Crawling, walking, and kneeling, leading to dermal uptake via the exposed skin; and
3. General day-to-day indoor activities, leading to the inhalation of fibers, dust, and tPCB vapors suspended in the air.

The extent of contact between children and carpet-borne constituents of concern is calculated via a deterministic exposure model. This model considers ingestion, dermal uptake, and inhalation exposure routes. The model and the associated input parameters are discussed below.

2.1 Exposure Model

To calculate the acceptable concentration of tPCBs in carpet by adopting child-specific exposure parameters and USEPA-promulgated, PCB-specific, non-cancer reference doses and cancer risk slope factors, an algorithm based on USEPAs (2002) guidance was modified to assess the carpet fiber exposure scenario.

2.1.1 Non-Cancer Hazard

The combined exposures calculation model for non-cancer hazard is as follows:

$$CNC_{Carpet} = \frac{THQ \cdot BW \cdot AT_{nc}}{ED \cdot EF\left[\left(\frac{1}{RfD} \cdot \frac{IR \cdot BioAF}{10^6 mg/kg}\right) + \left(\frac{1}{RfD} \cdot \frac{SA \cdot AF \cdot DERM}{10^6 mg/kg}\right) + \left(\frac{1}{RfD} \cdot IHR \cdot \frac{1}{VF} \cdot RF\right)\right]} \qquad \text{Equation 1}$$

where,

CNC_{Carpet}-risk-based concentration in carpet fiber associated with hazard quotient of 1 (mg/kg),

THQ-target hazard quotient (unitless),

BW-body weight (kg)

RfD-non-cancer reference dose (mg/kg BW/day),

AT_{nc}-non-cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm^2/day),

AF-dust adherence factor (mg/cm^2),

DERM-dermal absorption factor (unitless),

IHR-inhalation rate (m^3/day),

VF-volatilization factor (m^3/kg), and

RF-retention factor (unitless).

The volatilization factor (VF) used in the above equation was calculated via a set of concentration relationships derived experimentally for an enclosed chamber containing a carpet sample impregnated with a substance of interest (Bennet and Furtaw, 2004 citing Won et al., 2000). The relationships describing carpet surface to air partitioning (K_{SA}) are as follows:

$$K_{SA} = \frac{\frac{k_s}{k_d}}{d_w} = 10^{3.82 - 0.62 \log VP} \qquad \textbf{Equation 2}$$

where,

$$\frac{k_s}{k_d} = \frac{M}{C_g} \qquad \textbf{Equation 3}$$

substituting Equation 3 into Equation 2 and solving for M yields,

$$M = (d_w \cdot 10^{3.82-0.62\log VP} \cdot C_g) \qquad \textbf{Equation 4}$$

where,

k_s-adsorption coefficient (m/hr),

k_d-desorption coefficient (m/hr),

d_w-carpet thickness (m),

VP-vapor pressure (Pa),

C_g-acceptable concentration of PCBs in air from Equation 1 and 9 (mg/m^3), and

M-mass of PCBs per area of carpet (mg/m^2).

To express M on carpet weight basis (M_{cw}; mg/kg), this parameter can be divided by carpet face weight (FW; kg/m^2) such that

$$M_{cw} = \frac{(d_w \cdot 10^{3.82-0.62\log VP} \cdot C_g)}{FW} \qquad \textbf{Equation 5}$$

Furthermore, in realistic conditions of a normal house, ventilation is provided to maintain proper air quality. Therefore, the M_{cw} term must allow for a dilution factor (AE; unitless) to avert modeling unrealistically high concentrations. Thus, Equation 5 is modified to

$$M_{cw} = \frac{d_w \cdot 10^{3.82-0.62\log VP} \cdot C_g \cdot AE}{FW} \qquad \textbf{Equation 6}$$

The volatilization factor (VF; m^3/kg) is derived by dividing M_{cw} by the air concentration term C_g (Equation 7). The VF is inserted into Equation 1 to calculate an acceptable carpet concentration attributable to tPCB volatilization.

$$VF = \frac{M_{cw}}{C_g} = \frac{(d_w \cdot 10^{3.82-0.62\log VP} \cdot AE)}{FW}$$ **Equation 7**

Given that C_g is calculated in Equation 1 and 9 using the inhalation exposure assumptions, VF is inserted in these equations to derive an acceptable concentration in carpet fiber (M_{cw}; mg/kg).

$$VF*C_g = M_{cw}$$ **Equation 8**

Calculations were repeated for bioavailability factors of 0.01, 0.05, 0.1, 0.5, and 1 and for retention factors (RF) of 0.001, 0.005, and 0.01. The RF is used to model the proportion of tPCBs that may be liberated from the interior of the fiber as opposed to fiber surfaces alone. The bioavailability factor accounts for consideration of differences in absorption efficiencies of carpet-bound tPCBs via the gut. The reason for handling these parameters as variables is described in the Uncertainty section of this report (Section 4). The input variable parameterization is summarized in Section 2.2, as well as in Table 1.

2.1.2 Cancer Risk

The combined exposures back-calculation model for cancer risk is as follows:

$$CC_{Carpet} = \frac{TR \cdot BW \cdot AT_c}{ED \cdot EF\left[\left(\frac{CSF \cdot IR \cdot BioAF}{10^6 mg/kg}\right)+\left(\frac{CSF \cdot SA \cdot AF \cdot DERM}{10^6 mg/kg}\right)+\left(CSF \cdot IHR \cdot \frac{1}{VF} \cdot RF\right)\right]}$$ **Equation 9**

where,

CC_{Carpet}-risk-based concentration in carpet associated with 1 x 10^{-6} cancer risk (mg/kg),

TR-target cancer risk,

BW-body weight (kg)

CSF-cancer slope factor (mg/kg BW/day)$^{-1}$,

AT_c-cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm^2/day),

AF-dust adherence factor (mg/cm^2),

IHR-inhalation rate (m^3/day),

DERM-dermal uptake factor (unitless),

VF-volatilization factor (m^3/kg), and

RF-retention factor (unitless).

Calculations for cancer risk were also repeated for bioavailability factors of 0.01, 0.05, 0.1, 0.5, and 1, as well as for retention factors of 0.001, 0.005, and 0.01.

2.2 Model Parameterization

The exposure parameters, models, concentration data, risk factors, and assumptions used in the current assessment were obtained from a number of sources, including USEPA guidance documents, published literature, the internet, and Clariant's database. Input parameters are summarized in Table 1. The paragraphs below discuss each input parameter in detail.

2.2.1 Body Weight

The receptor of interest in the carpet scenario is a young child who is expected to be in direct contact with carpeted surfaces as a result of normal daily activities, such as playing, walking, and crawling. The range of age within this group can conceivably span from 1 to 10 years. The calculated average body weight for children of that age is 21.8 kg (USEPA, 2000) (Table 1).

2.2.2 Temporal Parameters

The time scale of the exposure and risk estimate is set to coincide with the useful life span of a residential carpet. According to an industry source, carpet warranties may span from 5 to 20 years. However, a typical carpet lasts about 10 years (Bigger and Bigger, 2004). Therefore, the exposure duration in this assessment was assumed to be 10 years. This is equivalent to the 3,650 days used as the averaging time in non-cancer hazard calculations. For the cancer risk assessment, a default life expectancy of 70 years was used to derive the lifetime average daily dose (25,550 days) (USEPA 1997, 2002) (Table 1). The exposure frequency was set to the default of 350 days per year (USEPA 1997, 2002) and the event frequency at one event per day.

2.2.3 Ingestion Parameters

The primary mode of tPCB intake in this exposure scenario is assumed to be via the incidental ingestion of carpet fibers/dust as a result of the mouthing of carpet surfaces, toys, hands, and feet. Because no ingestion rate data for the carpet fiber were readily available in the published literature, a conservative assumption was made that the carpet fiber intake by children is comparable to that of soil dust. According to Moya et al. (2004), children consume an average of 193 mg of soil and dust per day. However, the authors also stated that the daily consumption of soil alone is 138 mg/day. Therefore, an average dust ingestion rate of 55 mg/day can be estimated by subtracting 138 mg/day from 193 mg/day. That value was used to approximate the daily fiber ingestion rate (Table 1). Using an average for some exposure variables, and not setting them all at their high-end values, is consistent with USEPA risk assessment guidance (USEPA, 1989). Nevertheless, this remains a conservative assumption because, unlike loose soil particles, carpet fibers are not easily displaced because they are designed specifically to hold fast to the carpet backing.

A bioavailability factor was introduced into this component of the exposure/risk model to account for the proportion of the tPCBs in carpet that may be dislodged via digestive tract activities. This factor was set to range from 1% to 100% (Table 1) due to uncertainty as to its real empirical magnitude. At this time, the bioavailability factor remains a data gap, and it is viewed as a crucial component of the overall risk assessment.

Recent studies suggest that the bioavailability of lipophilic compounds like tPCBs and dioxins are reduced when adsorbed to the soil matrix. Ruby et al. (2002) reported that the bioaccessibility (a surrogate for oral bioavailability) of low concentrations of polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) ranged from 19% to 34%. Similar results were reported by Hack and Selenka (1996) for PCBs in a "standardized gastro-intestinal model." Although carpet fibers may differ from soil in important

physical parameters affecting intestinal absorption, it is important to note that the tPCBs in the pigment are permanently encapsulated in the polymer shell of the fiber during the coloring process and are unlikely to be as easily mobilized off the fiber as they are in the soil matrix. Therefore, even the assumption of 1% "bioavailability" likely overestimates the fraction of tPCBs available for absorption.

2.2.4 Inhalation Parameters

The inhalation rate of the receptor was set at 10.4 m^3/day, which is the average estimate for children ranging in age from 1 to 10 years old (USEPA, 2000) (Table 1). Although PCBs are large molecules and have only limited volatility at room temperature, an assumption was made that some amount may enter the room air and be available to be inhaled. The tPCB vapor contribution to the overall exposure burden was estimated via a set of empirical models derived from air chamber experiments (Equations 2 to 4; Bennet and Furtaw, 2004). The required parameters in these models include carpet thickness, carpet area mass (also called face weight), and vapor pressure. Average carpet thickness was set to 0.0129 m, and face weight was set to 1,700,000 mg/m^2 based on information obtained from the carpet industry (RPA, 2004; Carpet USA, 2004) (Table 1). The vapor pressure parameter was set to 0.0069 Pa and consisted of a mean of all values for PCB congeners 44 and 70 reported in the compendium by MacKay et al. (1992) (Table 1). To account for dilution due to ventilation, an air dilution factor (AE) was added to Equation 6. The value of that factor was based on the average number of air exchanges in a residential dwelling over 1 week. According to Murray and Burnmaster (1995), a house receives, on average, 18 air exchanges per day. This estimate is very conservative because the current calculations implicitly assume that the tPCB load will be renewed (i.e, an inexhaustible source) in the carpet every 7 days over the carpet's life span of 10 years. In an actual house, there would be far more frequent ventilation rates and no possibility of tPCB replenishment.

The inhalation of tPCB-laden house dust containing carpet fibers was not explicitly accounted for in the exposure/risk models because initial calculations revealed that the relative contribution of tPCBs entering the receptor via this exposure route is exceedingly small even under the most conservative exposure assumptions. For example, assuming that 100% of the house dust consists of carpet fibers and that all of the tPCB fiber residue is available for uptake, the maximum concentration of tPCB available for uptake is 16.4 mg/kg dust. The maximum concentration of tPCBs in carpet fiber was estimated using pigment analysis results from Alta Labs (Table 2). The maximum concentration of tPCBs in tested pigments was 1,370 ppm. The maximum proportion of pigment in Masterbatch concentrate was 40%, and no more than 3% of that concentrate was added to carpet. Multiplying 1,370 ppm by 40% and 3% results in an estimated concentration of 16.4 ppm.

Long et al. (2000) reported that an average concentration of dust in a non-smoker's house is 3.6 $\mu g/m^3$. Multiplying that number by the daily inhalation rate of a child (10.4 m^3/day; Table 1) yields a daily dust inhalation rate of 37.4 µg dust/day or 3.7×10^{-8} kg dust/day. Because the dust is assumed to contain 16.4 mg tPCBs/kg, the daily tPCB intake is 6.1×10^{-7} mg/day. Normalizing to the body weight of 21.8 kg (Table 1) yields an intake rate of 2.8×10^{-8} mg tPCB/kg BW/day. This value is nearly three orders of magnitude below the non-cancer and cancer hazard thresholds. Clearly, the relative contribution of house dust to the inhalation exposure route (and hazard/risk) is exceedingly small and, consequently, does not warrant explicit consideration in the exposure/risk model.

2.2.5 Dermal Uptake Parameters

Young children may spend much of their time crawling, walking, and kneeling. In an indoor environment, this may translate into dermal uptake via the exposed skin on knees, elbows, hands, and feet. According to the USEPA (2000), the skin surface area available for contact during warm-weather play, with 32% of the total skin surface area exposed, is 2,763 cm^2/day (Table 1). The adherence factor, or the amount of material remaining on the skin after contact, is estimated at 0.00724 mg/cm^2 (USEPA, 2000). This value reflects soil adherence for children: post-activity; indoors; and on hands, arms, legs, and feet. Again, an assumption is made that carpet fibers behave similarly to soil particles. This represents an uncertainty in the assessment.

The USEPA's default value for the dermal absorption factor for tPCBs in soil of 14% (USEPA, 2001) was adopted as the default value in this screening-level risk assessment. A recent report by Mayes et al. (2002) demonstrated that the dermal absorption of tPCBs from soil may be lower, approximating only 4% of the applied dose. Although carpet fibers may differ from soil in important physical parameters affecting dermal absorption, manufacturing processes also impact the amount of tPCBs available for absorption. The tPCBs in the pigment are permanently encapsulated in the polymer shell of the fiber during the coloring process and are unlikely to be as easily mobilized off the fiber as they are in the soil matrix. Thus, use of the default dermal absorption factor is likely an overestimate. Although there are no empirical data to quantify the amount of tPCBs that might be liberated from the carpet fiber, anecdotal evidence indicates that this is unlikely to be a significant amount. Individuals in contact with carpet, even young children crawling on the material, never show evidence of color transfer. For example, in the case of these pigments, children do not exhibit red knees, which would be evidence of a direct and substantial transfer of the encapsulated pigments (and tPCBs) onto the skin. As such, assuming a dermal absorption of 14% of the applied tPCBs from carpet substantially overestimates the exposure from this pathway.

2.3 Hazard and Risk Reference Values

Because no toxicity reference information for PCB 44 or 70 was available, the Aroclor 1254 reference dose was used as a surrogate. This is a very conservative step because an Aroclor mixture usually contains congeners that are assumed to be more persistent and potent than PCB 44 or 70. This further increases the degree of conservatism in the current assessment. The non-cancer reference dose for Aroclor 1254 is 0.00002 mg/kg/day (USEPA, 2002). The cancer slope factor of 0.07 $(mg/kg/day)^{-1}$ represents the lowest risk and persistence category recommended by the USEPA (2002). This value was selected because congener-specific data collected by Alta Labs demonstrated that the tPCB mixture present in the pigment contains only 0.1% to 0.4% of congeners with greater than four chlorines (Table 2). The target risk used in the calculation was the low end of the USEPA's "acceptable risk range" of 1 in 1 million exposed individuals (1×10^{-6}) (USEPA, 1996, 1997, 2000) (Table 1). The target hazard quotient was set to 1.

2.4 Results and Discussion

According to the exposure/hazard model for non-cancer effects, the combined ingestion, inhalation, and dermal uptake may lead to allowable concentrations in carpet fiber ranging from approximately 8 to 132 mg tPCBs/kg, depending on the magnitude of the bioavailability and retention factors (Table 3; Figure 1). In contrast, the acceptable concentrations of tPCBs in carpet fiber associated with a 1 in 1 million cancer risk are much higher and range from approximately 39 to 660 mg/kg (Table 3; Figure 2). Comparing the tPCB concentrations estimated in the finished product (carpet; 16.4 mg/kg) to the results from the current assessments suggests that, even at 100% bioavailability and 1% retention, it is highly unlikely that any cancer risk responses will be triggered. This observation is made despite the excessive amount of conservatism built into the current screening-level risk assessment. Because many of the critical physical/chemical parameters dictating how pigments (and tPCBs) behave in carpet fiber are unknown, this uncertainty was accounted for by intentionally overestimating many of these important factors. Rather than viewing these results as accurate predictors of risk, the important fact is that, even applying these high-end assumptions, the levels of tPCBs measured in the red pigments represent little or no unacceptable cancer risk.

Inspection of the results table for non-cancer hazard calculations reveals that the estimated maximum concentration in the final product (16.4 mg/kg) exceeds the acceptable concentrations under six exposure conditions. These situations represent a matrix of oral bioavailability ranging from 50% to 100% and a retention factor ranging from 0.1% to 1%. However, the risk management implications of this finding are tentative because of the uncertainty associated with the estimate of the maximum carpet concentration, retention factor, and oral bioavailability. These uncertainties are described in Section 4 of this report.

3. Food Wrap Scenario

The second exposure scenario identified by the CEM as requiring a detailed analysis is the scenario where a polymer film is used as a food contact material. This exposure scenario is based on a dual-layer wrap product in which the tinted outer non-food contact layer of the wrap contains the affected pigment. The analysis of this scenario focuses on emulating the U.S. Food and Drug Administration (FDA) assessment published in the Federal Register Notice (62 Fed. Reg. 9365, March 3, 1997) for a pigment colorant in polymers intended for use in contact with food.

3.1 Federal Register Notice

The FDA evaluated the safety of Pigment Red 254 used as a colorant in polymers intended as packaging material for food (62 Fed. Reg. 9365, March 3, 1997). Pigment Red 254 could contain inadvertently generated PCBs as permitted under applicable regulations. However, the FDA concluded that there is a reasonable certainty that no harm from exposure to tPCBs would result from the proposed use of the pigment in food packaging. The agency stated that it would not expect that the inadvertent impurity (tPCBs) would become a component of food at other than extremely low levels. This conclusion of no risk was based on the upper-bound calculated human cancer risk of less than 7.5×10^{-13}. The actual lifetime-averaged individual exposure (and risk) to tPCBs is likely to be substantially less because very conservative assumptions were used to set the worst-case scenario employed by the FDA.

3.2 Pigment Red 144/214 in Cheese Wrap

We expect that any PCBs in Pigments Red 254 and 144/214 behave in a similar fashion, and it is very plausible that the methodology used by the FDA is applicable for both pigments. We repeated the risk analysis for Pigment Red 144 and 214 to capture the case-specific concentration of 1.1 mg tPCBs/kg in the film used to wrap cheese (BBL, 2004). The cheese food category encompasses cheeses such as blue, brick, camembert, brie, cheddar, gouda, edam, limburger, mozzarella, parmesan, Swiss, cream, and processed. Exposure parameters relevant to that food group were obtained from Smiciklas-Wright et al. (2002).

In the current assessment, a conservative assumption was made that the entire residue of tPCBs contained in the outer layer of the film would transfer through the inner layer to the food item instantly. Thus, assuming that each square inch of film contacts 10 grams of food (the FDA's standard assumption) and that the film face weight is 0.035 g/in^2 (Clariant, undated), the maximum concentration of tPCBs in the contacted food (cheese) is

0.00385 mg/kg cheese[1]. The actual amount and rate of the tPCB transfer are likely much lower because the pigment is contained in the separate outer layer, which is not in immediate contact with food. Also, it would be expected that, under refrigerated conditions, migration would occur only at a slow rate, if at all. Thus, it is probable that the pigment never becomes incorporated into the food material.

To estimate the tPCB exposure of a person eating cheese, the calculated tPCB concentration must be multiplied by the amount of cheese consumed by a typical consumer. According to Smiciklas-Wright et al. (2002), average consumption of cheese is 0.026 kg per person per day. Given the average body weight of an adult of 70 kg, the exposure rate to tPCBs is 0.0000014[2] mg tPCBs/kg BW/day.

3.3 Results and Discussion

Comparing the calculated exposure to the non-cancer hazard threshold of 0.00002 tPCBs mg/kg BW/day (Table 1) reveals that the worst-case cheese exposure is about 15-fold lower than the trigger associated with non-cancer effects.

To estimate cancer risk, the estimated daily exposure must be averaged over a lifetime. According to Smiciklas-Wright et al. (2002), the maximum consumption rate of natural cheese for all age groups and genders is 16.2%. Assuming that there are three meals per day, the number of eating occasions in one year equals to 1,095. Thus, the number of eating occasions where cheese is consumed equals 177.39. Assuming three meals per day, the annual rate of cheese consumption is equivalent to approximately 59 days. This number was used as the exposure frequency. Exposure duration was set to 70 years, and the averaging time was set to 25,550 days. Multiplying the daily exposure rate of 0.0000014 mg tPCB/kg BW/day by 59 days/year and 70 years and dividing the product by 25,550 days yields a lifetime-averaged exposure rate of 0.0000002 mg tPCB BW/day. In terms of the cancer risks (0.000014 mg tPCB/kg BW/day; Table 1), the estimated exposure resulting from cheese consumption is about 63 times lower than that needed to exceed the cancer level risk of 1 in 1 million.

This analysis shows that the potential exposure to tPCBs resulting from eating cheese wrapped in red film is very low and highly unlikely to result in any toxicological responses in the population at large.

[1] 1.1 mg tPCBs/kg film x 0.000035 kg film /in^2 film x 1 in^2 /0.01 kg food (cheese) = 0.00385 mg tPCB/kg food (cheese)
[2] 0.00385 mg tPCBs/ kg cheese x 0.026 kg cheese/person/day x person/70 kg = 0.0000014 mg tPCBs/ kg BW/day

4. Uncertainty

Because the current methodology required estimating exposure and toxicity, uncertainty is inherent in the risk assessment process. Uncertainty in this context is attributed to either a lack of knowledge (referred to as "incertitude") or natural variability. Incertitude can be addressed by collecting additional information (i.e., obtaining additional exposure-related data), while uncertainty attributable to natural variability cannot easily be reduced.

The performance of the quantitative assessment, and the development of risk-based tPCB concentrations associated with the exposure pathways identified as "complete" in the CEM, have a number of uncertainties. These uncertainties fall primarily in the category of incertitude and are attributable to a lack of knowledge or information. While some of the parameters used to characterize exposure were obtained from USEPA guidance documents or the published literature, many important inputs were based on best professional judgment. Similarly, not only were characterization variables estimated, but some of the more basic information, such as the actual concentration of tPCBs in a home carpet, was estimated or based on internal calculations. While this estimate was based on limited empirical data, the concentration in the carpet actually contacted by the hypothetical receptor was assumed to be reflective of a carpet containing 100% red pigment (Pigment Red 144 and/or 214). Although no surveys were conducted to bound the uncertainty associated with this assumption, it is unlikely that bright red carpet (i.e., approximating 100% red pigment) is actually used in a *household* setting. To the contrary, industry representatives indicate that red pigment would generally not be used as the sole colorant in household carpets. Making the assumptions that an individual was exposed only to bright red carpet, and that the carpet was composed entirely of fibers with Pigment Red 144 or 214, significantly overestimates the exposure to tPCBs and, therefore, the risks and hazards associated with this pathway. The magnitude of this overestimation cannot be quantified at this time, but it is undoubtedly substantial, perhaps ranging over several orders of magnitude. Indeed, if fibers containing Pigment Red 144 or 214 comprise only 10% of the carpets that were actually manufactured, the risk-based concentrations presented in Table 3 would increase by an order of magnitude based solely on this one variable.

Additionally, if the carpets that were actually manufactured using Pigment Red 144 or 214 were not used in residential settings (as assumed in this screening-level risk assessment) but, rather, in industrial settings, then the risk-based concentrations in Table 3 would increase as well. Non-residential uses eliminate frequently exposed young children as receptors of concern (the most heavily exposed receptor), thereby eliminating two high-end

pathways of exposure. These consist of constant, direct dermal contact with carpet and ingestion of tPCBs as a result of mouthing behavior.

Because of the unique nature of the hypothetical situation evaluated in the assessment, it was necessary to modify the standard default values and to adapt them to the conditions assumed in the scenario. While data characterizing the "carpet scenario" are not specified in any USEPA guidance document, certain assumptions were made based on best professional judgment. For example, it was assumed that the primary exposure pathways were ingestion of liberated fibers, dermal contact with the fibers in the carpet, and inhalation of tPCB vapors emanating from the carpet fiber. In reality, due to the specifics of the manufacturing processes the exposure pathways are likely to be insignificant. In producing colored carpets, the pigment is permanently encapsulated in the polymer shell of the fiber during the coloring process. This encapsulation process effectively reduces the potential for the pigment to mobilize off the fiber material. During the early phase of this project, Clariant determined that tPCBs could be effectively extracted from a polymer matrix only with a non-polar solvent such as hexane, and that using water for such extractions yielded no detectible levels of tPCBs. Therefore, the assumption that a significant amount of the pigment (and associated tPCBs) is released from the fiber and is free to be absorbed in the gastrointestinal tract, enter the skin, or volatilize into the surrounding air to be inhaled, is not based on any empirical data, but rather represents a worst-case exposure scenario.

Addressing uncertainty by overestimating certain parameters is a standard technique in the USEPA-promulgated process. However, making these assumptions in order to complete the assessment does not suggest that Clariant endorses, or has information to support, these exposure parameters. In fact, observational data suggest that pigments (and associated tPCBs) are not readily transferred directly from the fiber to the skin because individuals routinely in contact with carpet do not show obvious signs (i.e., color) on their skin or clothes. Likewise, significant transfer of pigment off the fiber would result in obvious fading over a relatively short period of time. Again, this is not routinely observed. Therefore, this direct transfer of tPCBs would not occur in quantities that might represent significant exposure (on the skin and ingested via hand-to-mouth activity), nor to the extent as assumed in this exposure model. Therefore, this direct transfer of tPCBs would not occur in quantities that might represent significant exposure (on the skin and ingested via hand-to-mouth activity).

Similarly, the retention factors used in the inhalation exposure model were based on best professional judgment because no empirical data are available. The assumed retention factors of 0.1% to 1% were based on consideration of the manufacturing and end-use conditions. As previously noted, the pigment is permanently

encapsulated in the polymer shell of the carpet fiber during the coloring process. This process would dramatically reduce any potential for PCB molecules to volatilize off the fiber.

The volatilization factor calculated here, using work by Bennet and Furtaw (2004), examines the dynamics of volatile substances from carpet in a closed system. It implicitly accounts for sorption/desorption dynamics. However, it deals only with surfaces of an applied film, and not carpet fiber matrix where the dye is encapsulated. Therefore, the RF is used to model the proportion of tPCBs that may be liberated from the *interior* of the fiber, where the VF (Equation 8) from Bennet and Furtaw (2004) account from movement from the *surface* of the carpet into air. Also, explicit in the model used to estimate air concentration, the amount of tPCBs in the fiber represents an infinite, inexhaustible source (i.e., the concentration term stays constant). Use of higher, physically unlikely, retention factors would require that tPCBs be replenished because volatilization rates of 10% or higher over a 10-year period would substantially reduce the source of tPCBs in the fiber. Assuming that these higher volatilization rates would require the development of a first-order decay function for use in the exposure model, this decay factor and higher volatilization rates would result in depleted tPCB concentrations in the fiber and, therefore, much lower air concentrations over time than those assumed in the current assessment.

An additional uncertainty includes the methodology used to model carpet concentrations that results in "acceptable" air concentrations. The model used (Bennett and Furtaw, 2004) derives equilibrium partition coefficients to various surface components. These values have traditionally been determined "by releasing a low concentration of the compound of interest into a nonreactive chamber and with a sample of the material (e.g., carpet) of interest, followed by a desorption period. The air concentration throughout the experiment is measured, and from this adsorption, desorption and partitional coefficients can be derived." Although somewhat applicable in this situation, the tPCB-containing pigment is permanently encapsulated in the polymer shell of the fiber during the coloring process. As a result, the simple aerial application of materials and the resulting flux, as described by Bennett and Furtaw model, will result in an overestimation of the volatilization of tPCBs.

There are also experimental data to support the use of these low volatilization rates. Qi (2003) reported that, on average, 5% of pure PCBs placed on glass volatilized into the air. Because this volatilization occurred under favorable conditions, it is considered a high-end estimate. Because the manufacturing process encapsulates the pigment in the polymer shell of the fiber, this upper estimate is not particularly relevant to the carpet exposure

scenario, although it does provide support for the selection of the volatilization rates used in the screeninglevel assessment.

One acknowledged data gap is associated with the above discussion. Because the colorization/encapsulation process is unique, there are no available data that can be directly extrapolated to the exposure scenario. Thus, perhaps the greatest source of uncertainty, in terms of impacting the estimate of an internal dose of tPCBs, is the amount of tPCBs liberated from the fiber that can be absorbed across biological membranes. Because of this uncertainty, the screening-level risk assessment used a range of bioavailability factors to estimate exposure. Based on manufacturing processes and observational data that illustrate that the pigments are tightly bound to the fibers, assumptions above even 10% are significantly overestimating exposure and, therefore, risk. However, additional data would be required to quantify the magnitude of this overestimation.

Other uncertainties that were addressed by conservative estimates include the assumption that fiber particles behave like soil in terms of estimating dermal exposures. Adherence factors, in particular, likely overestimate the amount that the fiber and the time that it is in direct contact with the skin. Similarly, in a house that is kept clean and vacuumed, the contribution of carpet fiber to the house dust would be minimal. Thus, the assumption of an ingestion rate of 55 mg/day is not based on any scenario-specific information, but rather is based on estimates from studies on children playing outdoors. Again, adopting this exposure factor likely overestimated dust ingestion.

5. Conclusions

The purpose of this screening-level risk assessment was to satisfy a request from the USEPA to provide a bounding estimate on the hypothetical risks and hazards that might have been associated with a one-time past use of red pigments produced by Clariant that were subsequently found to contain trace concentrations of tPCBs. These pigments are no longer produced or sold by the Clariant and are no longer being inserted into commerce, where they could potentially be contacted by the public. However, in order to attempt to place into context the upper bound estimate of theoretical risks associated with these past uses, risk-based concentrations associated with two scenarios with a potential for exposure to sensitive human receptors were developed. Based on a qualitative evaluation of all products and intermediates potentially containing the pigments, the exposure pathways selected for this evaluation were considered, in theory, the most quantitatively significant.

As noted in the Section 4, data specific to the exposure pathways analyzed in this report are limited. In attempt to account for this limited information, and to address any potential risks associated with the use of Pigment Red 144 and 214 in consumer products, theoretical exposures were intentionally overestimated. Even under these high-end exposure assumptions, the concentrations determined to be within the USEPA's acceptable cancer risk range were well above the maximum concentration of tPCBs estimated in final product (carpet). Some of the conservative exposure scenarios for non-cancer hazards (i.e., 50% oral bioavailability) indicated that the allowable carpet concentrations were lower than those estimated in the final product. However, given the redundant conservatism built into the assessment, it is likely the risks and hazards are overstated. Therefore, the current analysis suggests that there was no unacceptable risk, and that there are no obvious public health concerns associated with the pigments in consumer products.

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7. Tables

Table 1. Exposure and Risk Model Input Parameters

Parameter	Value	Source
General		
Exposed Population: Young Children (yrs)	1 to 10	USEPA (2000)
Body Weight (1 to 12 yrs old; kg)	21.8	USEPA (2000)
Carpet Life Span (yrs)	10	Bigger and Bigger (2004)
Exposure Duration (yrs)	10	equal to carpet life
Exposure Frequency (days/year)	350	USEPA (1997; 2002)
Life Expectancy (yrs)	70	USEPA (1997; 2002)
Averaging time: non-cancer (days)	3,650	USEPA (1997; 2002)
Averaging time: cancer (days)	25,550	USEPA (1997; 2002)
Ingestion		
Dust (soil) ingestion rate (children; mg dust/day)	55	Moya et al. (2004)
Bioavailability of PCBs in fiber (ingestion and inhalation; %)	1, 5, 10, 50, and 100	assumption
Inhalation		
Inhalation rate (1 to 10 yrs old; m^3/day)	10.4	USEPA (2000)
Complete air exchange rate (1/week; based on 18 exchanges/day)	126	Murray and Burnmaster (1995)
Vapor pressure of PCB 44/70 mixture (Pa)	0.0069	MacKay et al. (1992)
Carpet thickness (m)	0.01286	RPA (2004)
Carpet area mass (face weight; mg/m^2)	1,700,000	Carpet USA (2004)
Retention factor (unitless)	0.001 to 0.01	Assumption
Dermal		
Dust adherence factor for children post-activity indoors on hands, arms, legs, feet (mg/cm^2)	0.00724	USEPA (2000)
Contact skin surface area during warm-weather play with 32% skin exposed (cm^2/day)	2,763	USEPA (2000)
Dermal uptake factor	0.14	USEPA (2001)
Hazard and Risk Reference Values		
Target hazard quotient	1	USEPA (1997; 2002)
Non-cancer reference dose (mg/kg BW/day)	0.00002	USEPA (2002)
Cancer slope (mg/kg BW/day)$^{-1}$	0.07	USEPA (2002)
Target cancer risk	1×10^{-6}	USEPA (1997; 2002)
Target lifetime average daily dose (mg/kg BW/day)	0.000014	equal to acceptable risk over cancer slope

Table 2. Results of Alta Labs Analysis of PCB Congener Composition in Pigment Red 114/ 214

Lot Sample	US62253701	USEA000373	US62254106	US63385702	US63385703	US63385704	US63385705	USEA000164	USEA000165
PCB Homolog (Congener Range)	%	%	%	%	%	%	%	%	%
mono (1-3)	0.0016	0.0055	0.00089	0	0	0	0.00067	0.00090	0
di (4-15)	0.010	0.013	0.011	0.0058	0.0048	0.0044	0.0064	0.0050	0.0053
tri (16-39)	0.53	0.65	0.55	0.34	0.31	0.36	0.37	0.36	0.37
tetra (40-81)	99.091	98.94	99.059	99.41	99.49	99.38	99.44	99.52	99.44
penta (82-127)	0.34	0.37	0.36	0.23	0.18	0.25	0.18	0.093	0.17
hexa (128-169)	0.023	0.024	0.018	0.0093	0.0090	0.013	0.0072	0.012	0.0093
hepta (170-193)	0.00020	0	0	0	0	0	0	0.00016	0
octa (194-205)	0	0.000079	0	0	0	0	0	0.000091	0
nona (206-208)	0.00013	0	0	0	0	0	0	0.000011	0
deca (209)	0	0	0	0	0	0	0	0	0
Total	100	100	100	100	100	100	100	100	100
Total Mono-Tetra	99.63	99.61	99.62	99.76	99.81	99.74	99.82	99.89	99.82
Total Penta-Deca	0.37	0.39	0.38	0.24	0.19	0.26	0.18	0.11	0.18

Table 2. Cont.

Lot Sample	USEA000303	US62253702	US62253721	US62313816	MXSC313501	MXSC313502	US63268101	US63268102	US63268103
PCB Homolog (Congener Range)	%	%	%	%	%	%	%	%	%
mono (1-3)	0	0	0	0	0	0	0	0	0.0043
di (4-15)	0.0044	0	0.0025	0.0017	0.0021	0.0019	0.019	0.0050	0.0079
tri (16-39)	0.26	0.38	0.37	0.39	0.37	0.38	0.30	0.24	0.25
tetra (40-81)	99.52	99.39	99.38	99.38	99.48	99.47	99.46	99.53	99.52
penta (82-127)	0.20	0.22	0.24	0.21	0.14	0.15	0.21	0.22	0.21
hexa (128-169)	0.0091	0.014	0.011	0.016	0.0090	0.0090	0.014	0.0082	0.0091
hepta (170-193)	0	0	0	0	0	0	0	0	0
octa (194-205)	0	0	0	0	0	0	0	0	0
nona (206-208)	0	0	0	0	0	0	0	0	0
deca (209)	0	0	0	0	0	0	0	0	0
Total	100	100	100	100	100	100	100	100	100
Total Mono-Tetra	99.79	99.77	99.75	99.77	99.85	99.85	99.77	99.77	99.79
Total Penta-Deca	0.21	0.23	0.25	0.23	0.15	0.15	0.23	0.23	0.21

Table 2. Cont.

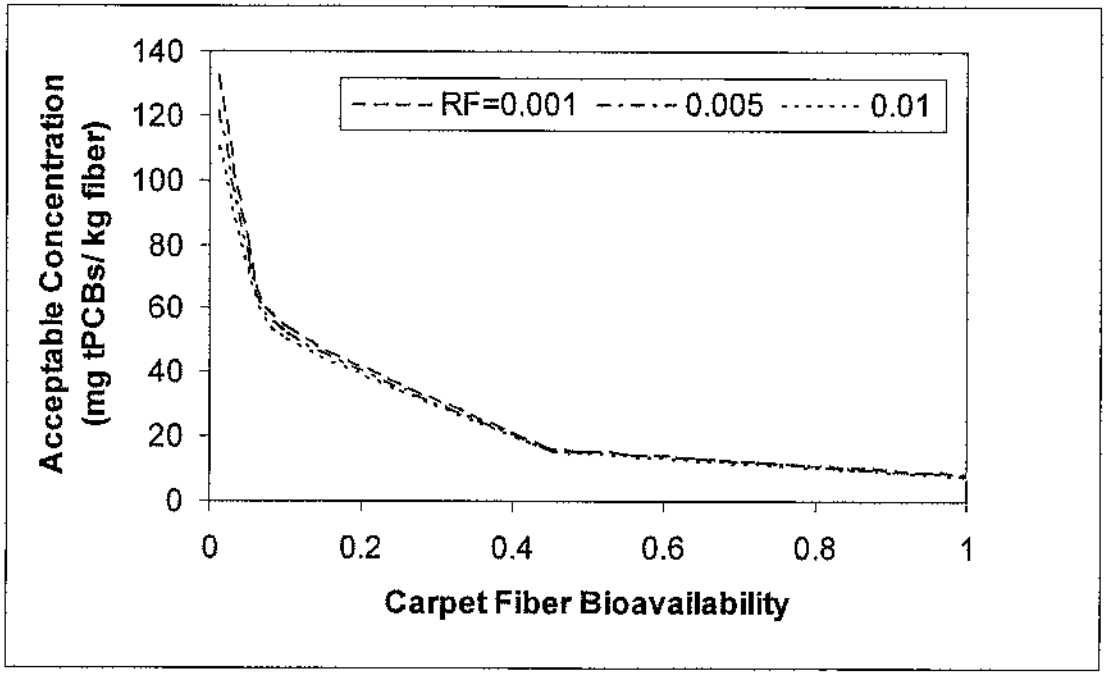
Lot Sample	US62253719	US62253711	US63268104	US63385701	US63385706	USEA000302	USEA000166	USEA000166(dup)
PCB Homolog (Congener Range)	%	%	%	%	%	%	%	%
mono (1-3)	0.00079	0.0028	0.032	0.00088	0.00084	0.00051	0.00070	0.00056
di (4-15)	0.0089	0.010	0.035	0.018	0.0066	0.0076	0.0085	0.0079
tri (16-39)	0.39	0.36	0.37	0.39	0.33	0.36	0.43	0.47
tetra (40-81)	99.29	99.29	99.16	99.24	99.43	99.32	99.31	99.25
penta (82-127)	0.30	0.33	0.39	0.33	0.22	0.29	0.24	0.25
hexa (128-169)	0.015	0.010	0.017	0.015	0.015	0.015	0.017	0.017
hepta (170-193)	0	0	0	0	0	0	0	0
octa (194-205)	0	0	0	0	0	0	0	0
nona (206-208)	0	0	0	0	0	0	0	0
deca (209)	0	0	0	0	0	0	0	0
Total	100	100	100	100	100	100	100	100
Total Mono-Tetra	99.69	99.66	99.60	99.65	99.77	99.69	99.74	99.73
Total Penta-Deca	0.31	0.34	0.40	0.35	0.23	0.31	0.26	0.27

Table 3. Risk-Based Concentrations (mg/kg) of tPCBs in Carpet Fiber

Oral Bioavailability Factor	Acceptable Concentration in Carpet Fiber (mg tPCB/kg)		
	Retention Factor		
	0.001	0.005	0.01
Non-Cancer Hazard			
0.01	133	122	111
0.05	81	77	72
0.10	54	52	50
0.50	15	15	15
1.00	7.9	7.8	7.8
Cancer Risk			
0.01	664	610	554
0.05	404	384	361
0.10	271	262	251
0.50	75	74	73
1.00	39	39	39

8. Figures

Figure 1. Risk-Based Concentrations of tPCBs in Carpet Fiber for the Non-Cancer Exposure Scenario Given Bioavailability and Retention Factors (RF)



Clariant

Clariant Corporation 4000 Monroe Road
Charlotte, NC 28205
704.331.7000

Via Fax (617) 918-0527 and FedEx 7916 0101 6359

April 15, 2005

Kimberly Tisa, PCB Coordinator (CPT)
U.S. Environmental Protection Agency
1 Congress Street, Suite 1100
Boston, MA 02114-2023

RE: Response to March 21, 2005 Comments on the Exposure and Screening-Level Risk Assessment, Red Pigment Project

Dear Ms. Tisa:

Clariant is writing to inform you of its response to the March 21st EPA and Versar comments on the document titled *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, February 2005.*

Two copies of the response accompanied by updated risk assessment reports are being overnighted to you today directly from Clariant's consultant, BBL Sciences. Therefore, you should receive them separately from this letter on Monday April 18.

Please allow me to reiterate comments from our last correspondence with you concerning Clariant's desire for confirmation from the EPA of the appropriateness of the overall risk assessment approach. Although Clariant appreciates the detailed review being provided by the Agency and its consultant, we do not yet have an understanding of the acceptance of the risk assessment methods used to date. Furthermore, we are anxious to learn whether the Agency and its consultant fully appreciate the conservative assumptions made in an effort to streamline the assessment process and the effects that they have had on over-stating the risks associated with this issue, possibly to a very significant extent. Clariant would like to direct your attention to the "Uncertainty" section of the report for a more detailed discussion on this point.

Clariant

We believe the most efficient way to address these concerns is to organize a meeting between EPA, Clariant and the two risk assessment consultants. Please let me know if you agree with this proposal, and if so, what dates you may have available for such a meeting in the near future. I can be reached at 704-331-7104 or via email at mike.teague@clariant.com

Sincerely,

CLARIANT CORPORATION

Michael A. Teague, Ph.D.
Vice President / ESHA

Enclosures

cc: Erin Russell, Esq.
John Schell, Ph.D.
John Paul
Robert Freet, Ph.D.

MEMORANDUM

To: Mr. Jim Buchert, Versar, Inc.

From: Laura Casey, OPPT/NPCD/FOB

RE: Technical Direction to Work Assignment 0-1

Subject: Clariant Corporation, Coventry, Rhode Island

EPA-Region 1 has received from the Clariant Corporation its response to Versar's March 18, 2005 comments on the *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios* dated February 2005 (*Exposure Assessment)* associated with Clariant's Red Pigments. Clariant has also provided a revised *Exposure Assessment* incorporating Versar's comments, as applicable. EPA will provide both the response and the revised *Exposure Assessment* to Versar under separate cover.

Please review these documents for the following:

- Please review the response and the revised *Exposure Assessment* and determine if Clariant has adequately addressed Versar's comments from March 18, 2005 .

Due Date: Please turn the review of these documents around by **May 13, 2005**. If there are any questions regarding this due date, please contact me at 202-566-1982.

Technical questions relating to this project may be addressed directly to Kim Tisa in Region 1 at 617-918-1527 or by e-mail at tisa.kimberly@epa.gov.

Clariant Corporation

4000 Monroe Road
Charlotte, NC 28205
704.331.7000

Via Fax (617) 918-0527 and FedEx 7916 0101 6359

April 15, 2005

Kimberly Tisa, PCB Coordinator (CPT)
U.S. Environmental Protection Agency
1 Congress Street, Suite 1100
Boston, MA 02114-2023

RE: Response to March 21, 2005 Comments on the Exposure and Screening-Level Risk Assessment, Red Pigment Project

Dear Ms. Tisa:

Clariant is writing to inform you of its response to the March 21st EPA and Versar comments on the document titled *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, February 2005.*

Two copies of the response accompanied by updated risk assessment reports are being overnighted to you today directly from Clariant's consultant, BBL Sciences. Therefore, you should receive them separately from this letter on Monday April 18.

Please allow me to reiterate comments from our last correspondence with you concerning Clariant's desire for confirmation from the EPA of the appropriateness of the overall risk assessment approach. Although Clariant appreciates the detailed review being provided by the Agency and its consultant, we do not yet have an understanding of the acceptance of the risk assessment methods used to date. Furthermore, we are anxious to learn whether the Agency and its consultant fully appreciate the conservative assumptions made in an effort to streamline the assessment process and the effects that they have had on over-stating the risks associated with this issue, possibly to a very significant extent. Clariant would like to direct your attention to the "Uncertainty" section of the report for a more detailed discussion on this point.

Clariant

We believe the most efficient way to address these concerns is to organize a meeting between EPA, Clariant and the two risk assessment consultants. Please let me know if you agree with this proposal, and if so, what dates you may have available for such a meeting in the near future. I can be reached at 704-331-7104 or via email at mike.teague@clariant.com

Sincerely,

CLARIANT CORPORATION

Michael A. Teague, Ph.D.
Vice President / ESHA

Enclosures

cc: Erin Russell, Esq.
John Schell, Ph.D.
John Paul
Robert Freet, Ph.D.

Clariant Corporation

4000 Monroe Road
Charlotte, NC 28205
704.331.7000

APR 1 2005

Via FedEx
7915 8808 9169

March 31, 2005

Kimberly Tisa, PCB Coordinator (CPT)
U.S. Environmental Protection Agency
1 Congress Street, Suite 1100
Boston, MA 02114-2023

RE: Schedule for Response to 3/21/05 Comments on Exposure and Screening-Level Risk Assessment, Red Pigment Project

Dear Ms. Tisa:

Clariant is responding to your letter dated March 31, 2005, which Clariant received on March 24, 2005, in which EPA provided comments to the February *2005 Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214*. You have requested that Clariant provide the Agency with an estimated schedule for making any necessary revisions to the risk assessment report based on the most recent comments.

Clariant's consultant, BBL Sciences, has reviewed the latest comments and has indicated that a revised report will be available for submission to the Agency no later than April 15, 2005.

You will recall from Clariant's last correspondence that certain discrepancies were identified in the quantitative data obtained from Clariant's internal laboratory and Alta Analytical Laboratory, Inc. Although we have attempted to understand and explain these discrepancies, no clear conclusions could be reached as to why the two analytical methods sometime produce significantly different results for the same pigment sample. Therefore, the most conservative approach going forward is to use the highest concentration value obtained for each pigment lot, regardless of the source of the data. Clariant will use the time from now until the revised report is ready to more accurately determine the impact of this approach on the estimate of contaminant concentration in carpet fiber.

You will note that the risk assessment was conservatively developed to yield a range of acceptable contaminant concentrations in carpet fiber for cancer and non-cancer risks (see Table 3 of the report). This method allows for any fiber concentration to be compared with the acceptable concentrations under various assumptions regarding bioavailability and retention factors. Clariant notes that, although EPA has commented on specific aspects of the risk assessment report, there has not yet been an opinion

rendered by the Agency as to the adequacy and acceptability of the overall approach being taken. In order for any meaningful conclusions to be drawn, Clariant requests that the Agency comment on the acceptability of the method and all of its stated uncertainties (see Section 4). It is very important that the Agency understand the impact of the uncertainties, because Clariant believes that these uncertainties significantly bias the evaluation toward a high-end or even worst-case estimate of risk. But in order to take the next steps toward closure on this issue, Clariant would like to be reassured that the approach so far is acceptable to the Agency. If there are outstanding considerations that the Agency would like Clariant to address, we would appreciate learning of them as soon as practicable.

Clariant is open to and would welcome a face-to-face meeting between its consultant and EPA's consultant to foster a more effective dialogue regarding the technical issues of the risk assessment, as well as to assure both parties that a resolution to this matter is on track and in sight. I look forward to hearing from you regarding this suggestion at your earliest convenience. In the meantime, should you have any questions or need additional information, please feel free to contact me at 704-331-7104 or at mike.teague@clariant.com

Sincerely,

CLARIANT CORPORATION

Michael A. Teague, Ph.D.
Vice President / ESHA

cc: Erin Russell, Esq.
John Schell, Ph.D.
John Paul
Robert Freet, Ph.D.

BBL®
BLASLAND, BOUCK & LEE, INC.
engineers, scientists, economists

April 15, 2005

Michael Teague, Ph.D.
Clariant Corporation
4000 Monroe Road
Charlotte, North Carolina 28205

Dear Dr. Teague:

We have reviewed the comment by USEPA and their contractor on the February, 2005 revision of *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214*. We agree with the comments submitted to us and remain appreciative of the thorough review of the submitted report. Where noted, the text was revised in the draft report, and in some instances changes were made to reflect concerns raised by the reviewers. I provide a specific response to each comment and identify how, where necessary, the document was modified.

Comment 1. The volatilization factor VF, calculated in this assessment is presented with the units of kg/m^3. A unit analysis of 3 of the equations seems to contradict this.

Response: The typographical error citing VF in text as having units of kg/m^3 was corrected. The correct units cited in text should have been m^3/kg.

Comment 2. Where does room surface area fit into these calculations? Is a certain area incorporated in the empirical equation used (Equation 2)? Typically, when an air concentration is calculated from soil or groundwater, the area of the source needs to be known and is incorporated into the calculation because a larger area results in a higher concentration.

Response: The surface area of the carpet is implicitly included in the relationship described in Bennet and Furtaw (2004) and in Won *et al.* (2000). The assumption is that room proportions (surface area to volume) are kept constant so the concentration would not change with the larger area of the carpet (i.e., room volume would increase proportionally).

Additional modification in the report: Maximum Concentration in Carpet Fiber.
A new maximum concentration of tPCBs in carpet fiber has been incorporated into our analysis of exposure and risk based on the recent analytical results from Alta Labs (Table 2 of the report). The maximum concentration of tPCBs in tested pigments was 1,370 ppm. The maximum proportion of pigment in Masterbatch concentrate was 40%, and no more than 3% of that concentrate was added to carpet. Therefore, multiplying 1,370 ppm by 40% and 3% yields an

estimated concentration of 16.4 ppm. Based on customer survey information, this defines an absolute worst-case condition, and one which has not yet been confirmed to actually exist. However, this high-end estimated concentration was considered in our analysis.

Once again, we would like to thank USEPA for their careful and a very constructive review and we welcome further dialogue to resolve any outstanding issues. If you have any questions, please do not hesitate to contact me at your convenience.

Sincerely,

John D. Schell, Ph.D.
Principal/Toxicologist

Cc: Kimberly N. Tisa, USEPA

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Figure 2. Risk-Based Concentrations of tPCBs in Carpet Fiber for the Cancer Exposure Scenario at Given Bioavailability and Retention Factors (RF)